

## **REMARKS**

In view of the above amendments and the following remarks, reconsideration of the rejections contained in the Office Action of October 16, 2008 is respectfully requested.

By this Supplemental Amendment, claims 39, 49, 56, 62 and 69 have been amended. Thus, claims 39-76 are currently pending in the application. No new matter has been added by these amendments.

It is noted that the remarks submitted in the Amendment filed on March 16, 2009 are re-presented below, but have been modified in view of the amendments to the claims as identified above.

On page 2 of the Office Action, the Examiner objected to claim 6 as containing an informality. However, as indicated above, claim 6 has been cancelled. It is noted that the identified informality does not appear in claims 39-76. Accordingly, it is respectfully submitted that the Examiner's objection is not applicable to claims 39-76.

On page 3 of the Office Action, the Examiner rejected claims 1-38 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner asserted that the phrase "in a direction substantially conforming to a tangential direction" is indefinite. In this regard, it is noted that claims 39-76 have been drafted to recite "a substantially tangential direction at a pressurization zone of the pair of press rolls," and it is noted that this limitation is clearly described, for example, on page 39 of the original specification. Accordingly, it is respectfully submitted that the Examiner's rejection under § 112 is not applicable to claims 39-76.

On pages 4-9 of the Office Action, the Examiner rejected claims 1-38 under 35 U.S.C. § 103(a) as being unpatentable over Roreger et al. (WO 02/51815) (using US 6,818,087 as a translation) in view of Nogami (WO 02/87622) (using US 2004/0137040 as a translation). However, as indicated above, claims 1-38 have been cancelled and replaced with claims 39-76. For the reasons discussed below, it is respectfully submitted that the claims are clearly patentable over the prior art of record.

Independent claims 39, 49, 56 and 62 each recite a method for producing an orally administrable edible agent of laminate film form. The methods of claims 39, 49, 56 and 62 include forming a plurality of orally administrable edible agent layers, wherein each orally

administrable edible agent layer is formed on a surface of a respective resin film by coating and drying. Further, the methods of claims 39, 49, 56 and 62 include joining together two orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding resin films of the two orally administrable edible agent layers, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers.

Further, the methods of claims 39, 49, 56 and 62 include delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction.

Roreger discloses a method for producing a laminated sheet matrix which contains a releasable ingredient. In particular, Roreger discloses that an active ingredient is applied to a base layer 1 by an applicator nozzle 12, and that a base layer 2 is laminated on the base layer 1 so as to seal the active ingredient within the base layers 1, 2 for maturation.

As an initial matter, it is noted that independent claims 39, 49, 56 and 62 recite forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer is formed on a surface of a respective resin film. In this regard, on pages 4-6 of the Office Action, the Examiner notes that the protective layers 3, 4 of Roreger correspond to the resin films of the claimed invention. However, it is noted that Roreger discloses that the active substance is applied to a surface of the base layer 1, and does not disclose that the active substance is applied to a surface of the protective layers 3 or 4. Thus, it is respectfully submitted that the protective layers 3, 4 do not correspond to the resin films of independent claims 39, 49, 56 and 62.

In this regard, it is noted that Roreger discloses that the base layers are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (column 5, line 66 through column 6, line 5), and therefore does not disclose or suggest delaminating only one of the two resin films (*i.e.*, the films having the surface on which the orally administrable edible agents are formed).

Further, even if the protective layers 3 and 4 are properly considered to correspond to the resin layers of independent claims 39, 49, 56 and 62, Roreger does not disclose *delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers* in a substantially tangential direction at a pressurization zone of the pair of press rolls, and *drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers* in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction *while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction*, as required by independent claims 39, 49, 56 and 62.

In particular, Roreger discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance (column 4, lines 46-49). Thus, Roreger does not disclose delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers, as required by independent claims 39, 49, 56 and 62, because Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance and therefore do not sandwich the active substance.

Further, Roreger does not disclose delaminating only one of the two resin films by drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction, as required by independent claims 39, 49, 56 and 62, because Roreger discloses that both of the protective layers 3 and 4 are removed, and that the protective layers 3 and 4 are removed prior to the application of the active substance and thus do not constitute resin films “sandwiching the” active substance.

Similarly, Roreger also does not disclose delaminating only one of the two resin films by drawing only one of the two resin films sandwiching the bonded orally administrable edible

agent layers in a direction different from the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction, as required by independent claims 39, 49, 56 and 62. Rather, as discussed above, Roreger discloses that both the protective layers 3 and 4 are removed prior to the application of the active substance, and therefore neither of the protective layers 3 and 4 constitutes a resin film retaining the bonded orally administrable edible agent layers.

In addition, with respect to independent claims 49 and 62, because Roreger does not disclose delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction, Roreger also does not disclose or suggest *joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers*, and *delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers*, as required by independent claims 49 and 62.

Additionally, Roreger does not disclose pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together *such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers*, as required by independent claims 39, 49, 56 and 62. Rather, Roreger discloses that the active ingredients on the base layers 1 and 2 diffuse into each other so as to form a homogenous matrix (see column 3, lines 42-25 and column 6, lines 38-41), and therefore does not disclose pressurizing the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers, as required by independent claims 39, 49, 56 and 62.

Further, as noted by the Examiner on page 8 of the Office Action, Roreger does not disclose an orally administrable edible agent of laminate film form. In this regard, the Examiner

cites Nogami as disclosing a layered edible film for administering an active agent, and concludes that it would have been obvious to one of ordinary skill in the art to make the layered edible film of Nogami by the method of Roreger so as to arrive at the claimed invention.

Nogami discloses an orally administered agent which includes a combination of drug-containing layers 11, water-swellaible gel-forming layers 12, and intermediate layers 13. However, Nogami does not disclose a method which includes delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction *while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction*, as required by independent claims 39, 49, 56 and 62.

In particular, Nogami does not disclose or suggest delaminating any layer of the orally administered agent, and therefore does not disclose or suggest delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction, as required by independent claims 39, 49, 56 and 62.

Further, Nogami does not disclose pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together *such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers*, as required by independent claims 39, 49, 56 and 62. Rather, Nogami discloses that the drug-containing layers are laminated together. In this regard, it is noted that Nogami is an example of the conventional lamination technique described on page 76 of the original specification in the present application. In particular, as described on

page 76 of the original specification, the boundaries of adjacent layers in the conventional lamination technique are blurred and unclear because when a preparation solution is applied to an adjacent layer in a laminated manner, the solvent of the preparation solution permeates the adjacent layer. Therefore, it is respectfully submitted that one of ordinary skill in the art would recognize that Nogami discloses a conventional lamination technique in which the solvent of an applied layer permeates an adjacent layer, and therefore does not disclose pressurizing the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers, as required by independent claims 39, 49, 56 and 62.

As indicated above, none of the Roreger and Nogami references discloses or suggests a method which includes (1) pressurizing the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers, (2) delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and (3) drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction, as required by independent claims 39, 49, 56 and 62. Accordingly, it is respectfully submitted that the combination of the Roreger and Nogami references does not disclose or suggest all of the limitations of independent claims 39, 49, 56 and 62.

Independent claim 69 recites a pressure bonding apparatus for producing an orally administrable edible agent of laminate film form, which includes a pair of press rolls arranged to draw two resin films, with each of the resin films being provided with an orally administrable edible agent layer having a predetermined thickness on a surface thereof, such that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between the resin films, and with the pair of press rolls being further

arranged to pressurize the resin films at back surfaces thereof so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers. The pressure bonding apparatus of claim 69 also includes a delamination roll having a diameter of 6 cm or less disposed at a position forward of the pair of press rolls in a conveying direction of the pair of press rolls and in a substantially tangential direction at a pressurization zone of the pair of press rolls.

Further, claim 69 recites a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers conveyed from the pair of press rolls to the delamination roll in a direction different from the conveying direction from the pair of press rolls to the delamination roll, along a peripheral surface of the delamination roll, and a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction from the pair of press rolls to the delamination roll.

As indicated above, Roreger discloses that an active ingredient is applied to a base layer 1 by an applicator nozzle 12, and that a base layer 2 is laminated on the base layer 1 so as to seal the active ingredient within the base layers 1, 2 for maturation.

However, Roreger does not disclose *a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers in a direction different from the conveying direction*, and does not disclose *a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction*, as required by independent claim 69.

Rather, as indicated above, Roreger discloses that the base layers are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (column 5, line 66 through column 6, line 5), and therefore does not disclose or suggest a winding shaft arranged to draw and delaminate only one of the two resin films (*i.e.*, the films having the surface on which the orally administrable edible agents are formed).

In addition, as also discussed above, Roreger discloses that the winders 5 and 6 remove both of the protective layers 3 and 4 prior to the application of the active substance, and therefore

does not disclose a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers, as required by independent claim 69.

Further, as discussed above, Roreger does not disclose *a pair of press rolls arranged to pressurize the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers*, as required by independent claim 69. Rather, Roreger discloses that the lamination unit 13 produces a laminated sheet matrix in which active ingredients on the base layers 1 and 2 diffuse into each other so as to form a homogenous matrix (see column 3, lines 42-25 and column 6, lines 38-41), and therefore does not disclose a pair of press rolls arranged to pressurize the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers, as required by independent claim 69.

Nogami discloses an orally administered agent which includes a combination of drug-containing layers 11, water-swellaable gel-forming layers 12, and intermediate layers 13. However, Nogami does not disclose a pressure bonding apparatus for producing an orally administrable edible agent, and also does not disclose a pressure bonding apparatus for producing an orally administrable edible agent which includes *a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers in a direction different from the conveying direction, and a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction*, as required by independent claim 69.

Further, Nogami does not disclose a pressure bonding apparatus which includes *a pair of press rolls arranged to pressurize the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers*, as required by independent claim 69. Rather, Nogami discloses that the drug-containing layers are laminated together. As discussed above, it is noted that one of ordinary skill in the art would recognize that



Nogami discloses a conventional lamination technique in which the solvent of an applied layer permeates an adjacent layer, and therefore does not disclose a pressure bonding apparatus which includes a pair of press rolls arranged to pressurize the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers, as required by independent claim 69.

As indicated above, none of the Roreger and Nogami references discloses a pressure bonding apparatus for producing an orally administrable edible agent which includes (1) a pair of press rolls arranged to pressurize the resin films so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers, (2) a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers in a direction different from the conveying direction, and (3) a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction, as required by independent claim 69. Accordingly, it is respectfully submitted that the combination of the Roreger and Nogami references does not disclose or suggest all of the limitations of independent claim 69.

Therefore, for the reasons presented above, it is believed apparent that the present invention as recited in independent claims 39, 49, 56, 62 and 69 is not disclosed or suggested by the Roreger reference and the Nogami reference taken either individually or in combination. Accordingly, a person having ordinary skill in the art would clearly not have modified the Roreger reference in view of the Nogami reference in such a manner as to result in or otherwise render obvious the present invention of independent claims 39, 49, 56, 62 and 69.

Therefore, it is respectfully submitted that independent claims 39, 49, 56, 62 and 69, as well as claims 40-48, 50-55, 57-61, 63-68 and 70-76 which depend therefrom, are clearly allowable over the prior art of record.

Further, it is noted that on page 9 of the Office Action, the Examiner indicated that claims 25 and 26 are substantial duplicates of claims 6 and 8, respectively. However, as noted above, claims 1-38 have been cancelled and replaced with claims 39-76. In this regard, it is noted that

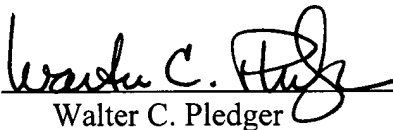
none of claims 39-76 are substantial duplicates of each other.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance. An early notice to that effect is respectfully solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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